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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,618	02/22/2002	Alan D. Olstein	7005-0003	4458

23980 7590 05/05/2003
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,618

Applicant(s)

OLSTEIN ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, and 65-67, drawn to complexes of bacteriocins and metals, classified in class 514, subclass 6.
 - II. Claims 10-17, and 57-64, drawn to methods of synthesizing complexes of bacteriocins and metals, classified in class 514, subclass 6.
 - III. Claims 18-32, and 68-70, drawn to methods of forming complexes of bacteriocins and metals on a sample to be tested, classified in class 514, subclass 6.
 - IV. Claims 33-38, 43, and 51-53, drawn to diagnostic tests relating to bacteria, classified in class 435, subclass 8.
 - V. Claims 39-42, 44-47, and 54-56, drawn to chemiluminescent assays or pathogens, classified in class 435, subclass 8.
 - VI. Claims 48-50, drawn to methods of treatment, classified in class 514, subclass 6.
 - VII. Claims 71 and 72, drawn to chemiluminescent agglutination assays, classified in class 435, subclass 8.

For each of Groups I-VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if one of Groups I-VI is elected, then election is also required to one each of Groups (A)- (D) and of Groups (1) or (2).

The inventions of Groups (A)-(D) represent the invention of the elected Group wherein the bacteriocin is

- (A) a lantibiotic;
- (B) a non-lanthionine peptide;
- (C) a large heat labile protein; or
- (D) a complex bacteriocin.

The inventions of Groups (1) and (2) represent the invention of the elected Group wherein the metal is

- (1) a transition metal; or
- (2) a lanthanide metal.

I.e., the applicant must elect a group of the claimed complexes.

For Group A above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and to one of Groups (A)-(D), and, if Group (A) is elected, then election is also required to one of inventions represented by the individual proteins listed in (e.g.) claim 6. (I.e. the Applicant must elect one of the proteins listed in that claim.)

For Group II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if Group II is elected, then election is also required to one of inventions II-a or II-b, and to one of inventions II-c or II-d. These inventions relate to the claimed method where

- II-a the desalting is performed by dialysis; or
- II-b the desalting is performed by gel filtration; and

- II-c the drying is performed by freeze drying; or
- II-d the drying is performed by spray-drying.

For Group VII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and, if Group VII is elected, then election is also required to one each of Groups VII-a or VII-b. The inventions of Groups VII-a and VII-b represent the invention of the elected Group wherein the metal is

- (VII-a) a transition metal; or
- (VII-b) a lanthanide metal.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions represented by the groups of complexes, or the specific proteins, or the subgroups VII-a and VII-b among which restriction is required above, are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, the different subcombinations each have the same utility as the combination. They are therefore each distinct one from the other.
3. The inventions of groups I, II, and III are related as product made, and processes of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, either of the claimed methods may be used to make the claimed product. As

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each of these methods has a different mode of operation, and is therefore distinct from the other, the product may be made by materially different processes. The product is therefore distinct from either of the processes.

4. The inventions of Groups I and of groups IV-VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product may be used in any of the claimed methods of performing assays or treatments. Each of these methods either has a different mode of operation, a different function, or both in comparison to the other methods. As the product may be used in any of these methods, the product is distinct from each of them.

5. The inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, each relate to a different method of making the same products. However, each of the methods performs the same function using a different mode of operation. As such, each method is distinct from the other.

6. The inventions of Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relates to a different method of using the claimed products for

performing an assay, or for a method of treatment. As these methods either perform different functions, or have different modes of operations, the methods are distinct each from the others.

It is noted that claims 33-38 appear not to describe a test, but a kit. However, as claim 43 depends from these claims, and as this claim refers to a method, the inventions of Group IV are being treated as method claims. It is further noted that each of Groups IV and V relate to methods of using the claimed product for a diagnostic purpose. However, as it is unclear what the method of Group IV entails, the method described therein is being treated as separate from those of Group V as having a different mode of operation for the purposes of this restriction requirement.

7. The inventions of Groups I-VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate either to claimed products or to methods of using or making such, or to a chemiluminescent assay for viruses or prions that involves the constituents, but not necessarily the complex of the product claims. As the claimed method relates to the use of a different product from the other claims the inventions of Group VII are distinct from the others.

It is also noted that the claimed method would also be distinct from the other Groups for the same reasons as presented with respect to the methods of using in Groups IV-VI, and the methods of using/product made, above.

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Species Election

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups (1) and (2) of the restriction groups defined above, the Applicant is further required to elect one of the claimed metals listed in either claim 4 or 5, as appropriate to the elected Group.

For Groups IV, and V, the Applicant is required to elect one of the listed species of claims 51 or 54 as appropriate, and if the Applicant elects a bacteria or a mycobacteria, the applicant is further required to elect one of the species listed in claims 52, 53, 55, or 56 as appropriate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 33, and 39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

9. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

10. It is here noted that some of the restrictions requirements made above fall within the scope of **PTO Linking claim practice**. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

11. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P.

§821.04 regarding the **restriction of claims to a product and processes of using the product**,

Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from

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further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


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12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
April 29, 2003


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
5/4/03